# Scleral Buckling Surgery For Stage 4A and 4B Retinopathy of Prematurity in Critically Ill Neonates.

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# Abstract

**Purpose**: To determine the efficacy of scleral buckling in eyes with stage 4A and 4B retinopathy of prematurity (ROP).

**Methods**: Seven eyes of five premature infants underwent scleral buckling for stage 4 ROP in zone II. Five eyes had stage 4A ROP, and two eyes had stage 4B ROP. Six eyes had previous diode laser photocoagulation, and one eye had received an intravitreal ranibizumab injection. Scleral buckling was the procedure of choice due to lack of access to specialized pediatric vitrectomy instrumentation. Average age at surgery was 3.4 months. Postoperative anatomic retinal status, visual acuity outcome and refractive error were assessed.

**Results**: The scleral buckle was removed on average 8 months after surgery. Retinal reattachment was achieved in all seven eyes. At final follow-up one eye had macular ectopia and disc dragging, one eye had a macular traction fold and two eyes had optic disc pallor. Average myopic error after buckle removal was -7.5 D.

**Conclusion**: Scleral buckling can be performed safely and effectively in 4A and 4B stage ROP in critically-ill infants, when access to specialized pediatric vitrectomy instrumentation is limited. This surgical technique may provide adequate relief of vitreoretinal traction with improved visual potential.


# Introduction

The advances in neonatal care and the increase in survival rates for extremely preterm babies are steadily raising the number of ROP treatments and the need to manage more advanced stages of the disease [1, 2]. Despite early management of retinopathy of prematurity (ROP) by means of laser ablation and intravitreal anti-vascular endothelial growth factor agents (anti-VEGF), a total of 12% of treated eyes will progress to stage 4 and 5 ROP needing surgical treatment [3]. Various surgical techniques have been employed for the treatment of retinal detachments associated with ROP, including scleral buckling (SB), open-sky vitrectomy, vitrectomy and lensectomy, and lens-sparing vitrectomy (LSV) [4]. SB surgery has been the conventional treatment of eyes with stage 4A and 4B ROP, and the mechanism of action has been the relief of vitreoretinal traction [5].

With the advances in newer microincision vitrectomy instrumentation, better reattachment rates have been reported for LSV compared to SB, as LSV relieves vitreoretinal traction by eliminating the scaffolding for further fibrovascular growth and removes growth factors that contribute to vascular activity [6, 7]. Additionally, the absence of induced myopia and the avoidance of a second procedure to remove the buckle have established LSV as the procedure of choice for stage 4 tractional retinal detachments associated to ROP [7, 8]. On the other hand, LSV requires specialized equipment for pediatric vitrectomy and a trained vitreoretinal surgeon. Hence, immediate access to facilities for pediatric vitrectomy is not available in all hospitals with neonatal intensive care units (NICUs).

In light of these issues, this study aimed to investigate the efficacy of SB in eyes with stage 4A and 4B retinopathy of prematurity in critically ill infants, who did not undergo vitrectomy due to lack of access to specialized pediatric vitrectomy instrumentation.

# Material And Methods

This study was a case series of 7 eyes of 5 premature infants with active 4A and 4B ROP, who underwent primary SB between October 2018 and November 2020 at a tertiary center (Larissa University Hospital). This hospital hosts a neonatal intensive care unit (NICU) that serves all central Greece, and is the only public institution in Greece that operates infants with ROP. Preoperative clinical assessment included demographic information, ophthalmic and medical history, indirect ophthalmoscopy with retinal drawings and fundus photography in selected cases. ROP staging was performed in accordance with the expanded international classification of ROP [9]. All surgeries were performed by one experienced vitreoretinal surgeon (SA) under general anesthesia after obtaining informed consent from the parents. For patients requiring bilateral treatment, the SB was performed in both eyes in one setting. The surgical technique entailed 360° circumferential placement of a solid silicone #240 band exoplant as close to the ridge as possible. The SB was sutured in each of the four quadrants with a single horizontal 5–0 Dacron scleral fixation suture, and tied with a #270 sleeve in the inferotemporal quadrant to create a circumferential buckle of moderate height. Anterior chamber paracentesis was performed as required. Subretinal fluid was not drained in any case. Anatomic success was defined as complete retinal reattachment for stage 4A and macular attachment (i.e. full attachment of the retina between the temporal vascular arcades) for stage 4B.

# Results

Preoperative data are summarized in Table 1. Average postoperative follow-up time was 26.4 months (range, 20–34 months). Average gestational age at birth was 27.5 weeks (range, 24–30 weeks). Two infants were extremely premature (ID1 and ID4). Average birth weight was 975 g (range, 530–1275 g). Average age at surgery was 3.4 months (range, 3–4 months). There were three males and two females. Before surgery all eyes had light perception acuity. Five eyes had stage 4A ROP, and two eyes had stage 4B ROP. Six eyes had previous diode laser photocoagulation for stage 3 + ROP in zone II, and one eye had received an intravitreal ranibizumab injection for stage 3 + ROP in posterior zone II. Despite the aforementioned treatment, retinal detachment was actively progressing, hence surgical intervention was decided. Scleral buckling was the procedure of choice due to lack of access to specialized pediatric vitrectomy instrumentation at that time. No intraoperative or perioperative complications occurred. No systemic complications relating to anesthesia were encountered.

Surgical results and anatomic outcomes are presented in Table 2. The scleral buckle was removed on average 6.6 months after surgery (range, 5–10 months). Retinal reattachment was achieved in all seven eyes. One eye developed macular ectopia, one eye had a macular traction fold and two eye developed partial optic atrophy. Postoperative anatomic retinal status, visual acuity outcome and refractive error were assessed in various timepoints for each patient. Refraction under cycloplegia was performed 45 minutes after instillation of cyclopentolate 1%. Individual patients' clinical course is presented below.

Table 1. Preoperative data.

| ID | Sex | Gestational age (wks) | Birth weight (gr) | ROP Stage (OD/OS) | Location of detachment | Age at surgery (months after birth) | Pre-OP therapy<br><br>(Laser/Inj ranibizumab) | Systemic comorbidities |
|---|---|---|---|---|---|---|---|---|
| 1 | M | $23^{+6}$ | 530 | 4A/3 | Temporal OD | 3.5 | Yes / Yes | Extreme prematurity, bronchopulmonary dysplasia, mechanical ventilation, CLABSI (Candida albicans), intraventricular hemorrhage, periventricular leukomalacia, anemia of prematurity, blood transfusion, late sepsis |
| 2 | M | 30 | 1275 | 3/4A | Superior OS | 3.5 | Yes / Yes | Bronchopulmonary dysplasia, mechanical ventilation, intraventricular hemorrhage, urinary tract infection (pseudomonas aeruginosa), anemia of prematurity, blood transfusion, late sepsis |
| 3 | F | $30^{+5}$ | 1080 | 4A/4A | Temporal OU | 3 | Yes / Yes | Bronchopulmonary dysplasia, pneumothorax, mechanical ventilation, anemia, blood transfusion, early sepsis |
| 4 | M | $25^{+5}$ | 750 | 4B/3 | Inferior quadrants OD | 4.5 | Yes* / Yes* | Extreme prematurity, severe bronchopulmonary dysplasia, mechanical ventilation, apnea, necrotizing enterocolitis stage II, hypoxic ischemic encephalopathy, spasms, osteopenia, anemia, blood transfusion, late sepsis |
| 5 | F | 28 | 1240 | 4A/4B | Temporal OD, all | 3 | Yes / Yes | Bronchopulmonary dysplasia, |

| | | |
|---|---|---|
| | quadrants OS | mechanical ventilation, surgery for necrotizing enterocolitis, periventricular leukomalacia, anemia, blood transfusion, late sepsis |

ROP = Retinopathy of prematurity; OD = right eye; OS = left eye; OU = both eyes; Pre-OP = preoperative; M = male; F = female; CLABSI = central line-associated bloodstream infection. * = Injection ranibizumab.

Table 2. Postoperative data at last follow-up.

| ID | Anatomic result | Anatomic description | Removal of SB (months post-OP) | Visual acuity of operated eye (OD/OS) | Refractive error (OD/OS) | Follow-up (months) |
|---|---|---|---|---|---|---|
| 1 | Attached | Temporal disc pallor | 5 | CSUM | -3 | 34 |
| 2 | Attached | Small localized superior retinal detachment | 6 | FF | -14 | 28 |
| 3 | Attached OU | Macular ectopia and disc dragging OD, disc pallor OS | 10 | FF/CSM | -4/-5 | 26 |
| 4 | Attached | Peripheral fold | 6 | FF | -11 | 24 |
| 5 | Attached OU | Small localized temporal retinal detachment and macular fold OS | 6 | FF/FF | -8/-7.50 | 20 |

SB = scleral buckle; post-OP = postoperative; OD = right eye; OS = left eye; OU = both eyes; CSUM = central, steady and maintained; FF = fix and follow, CSM = central, steady and unmaintained.

*Patient 1*

This patient had prior bilateral laser for stage 3 + ROP in zone II. Although the right eye underwent a second laser session, the disease progressed to stage 4A. He presented with a temporal tractional retinal detachment sparing the fovea. Three weeks after scleral buckling the retina flattened and gradually reattached. The buckle was removed after 5 months and temporal optic disc pallor was observed as sequela of retinopathy (Fig. 1). Visual acuity of the infant at last follow-up was light perception.

*Patient 2*

This patient had also prior bilateral laser for stage 3 + ROP in zone II, but progressed to stage 4A ROP with a superior tractional retinal detachment in the left eye. Two weeks after scleral buckling the retina partially reattached. The buckle was removed 6 months later. After 28 months of follow-up, he has retained a good anatomic result with a small confined, localized superior retinal detachment and a fix-and following vision.

*Patient 3*

This patient had prior laser in both eyes for stage 3 + ROP in zone II; however, ROP progressed to stage 4A with bilateral temporal exudative retinal detachment and cystoid macular edema in the left eye (Fig. 2). The patient was initially treated with topical cyclopentolate (0.5%), topical prednisolone acetate (1%) and intravenous dexamethasone for the exudative retinal detachment. Despite treatment, retinal detachment persisted and peripheral traction over the ridge started to develop, hence SB in both eyes was decided and was performed in one setting. By 3 weeks after buckling the peripheral detachment settled, the active retinopathy regressed, and the buckles were removed 10 months after surgery (Fig. 3A and 3B). The delay in removal of the buckles was due to recurrent upper respiratory tract infection of the patient that deemed general anesthesia as a risk. Although retinal reattachment was complete in both eyes, 26 months after buckle removal the right eye has macular ectopia and disc dragging and the left eye has optic disc pallor and peripapillary atrophy. At last follow-up visual acuity was fix-and-follow in the right eye and fixing but not following in the left. The patient has a left esotropia and does patching against amblyopia. Horizontal jerk nystagmus is also present.

*Patient 4*

This patient was referred from another institution having received bilateral intravitreal ranibizumab injections for stage 3 + in posterior zone II. ROP regressed in the left eye, but he developed stage 4B ROP in the right eye. He presented to us with an inferior retinal detachment involving the macula in the right eye. By one month after buckling, the retina reattached, and 6 months later appeared stable with a residual temporal fold not involving the macula, at which time removal of the buckle was performed. At last follow-up his visual acuity in the right (treated) eye was fix-and-follow.

*Patient 5*

This patient progressed to stage 4A ROP in the right eye and 4B ROP in the left eye despite laser ablation of the avascular retina in another institution. Preoperatively there was a temporal tractional detachment in the right eye and an extensive retinal detachment with tractional vitreous bands involving the macula in almost all quadrants of the left eye. SB was performed in both eyes in one setting. By 1 month after buckling the retina was completely attached in the right eye and the detachment became less bullous in the left eye. Buckle removal was performed 6 months after surgery, at which time in the right eye the retina was completely attached, and in the left eye the macula was fully attached with a localized shallow temporal retinal detachment in the periphery. At last follow-up 20 months after surgery, the right eye had a fix-and-following vision, and the left eye was fixing but not following, a macular traction fold and left esotropia.

# Discussion

The cornerstone of surgical intervention in stage 4 ROP is a combination of anatomic retinal reattachment and recession of vascular activity for optimal functional outcome [7, 10].

SB surgery was the treatment of choice for stage 4 ROP in the past [11, 12]. With the advent of new, more sophisticated technologies in vitreoretinal instrumentation, small-gauge LSV has largely replaced SB in stage 4 ROP, as there is evidence that it releases vitreoretinal traction more effectively [13]. Anatomic success after SB has been reported between 46% and 75%, [11, 12, 14, 15, 17] whereas after LSV between 80–90% depending on the stage of ROP, 4A or 4B [4, 13, 16–18]. The advantages of vitrectomy include releasing of vitreoretinal tractions, removal of endogenous vasodilators and angiogenic factors from the vitreous scaffold and prevention of fibrovascular membrane formation [5]. On the other hand, access to specialized equipment for pediatric vitrectomy is not universal and SB surgery may still have a role in the management of ROP-related retinal detachments with peripheral traction.

This study investigated the effectiveness of SB in stage 4A and 4B ROP in infants who did not undergo vitrectomy, due to lack of pediatric vitrectomy instrumentation. In all seven eyes, SB led to regression of vascular activity, which was evident by disappearance of the neovascular tufts in the detached ridge and recession of plus disease. Gradually the retina reattached and the funduscopic appearance remained stable for several months after SB removal. The anatomic outcome was favorable in all cases. At last follow-up there was complete retinal reattachment in five eyes and residual small peripheral retinal detachments without evidence of traction in two eyes. One eye had macular and disc dragging and one eye had a macular traction fold. Regarding the functional outcome, five of seven eyes achieved a fix and follow vision, one eye had central steady and maintained fixation and one eye had central steady and unmaintained fixation. The anatomic result was maintained for an average postoperative follow-up time of 26.4 months.

The favorable outcomes of this study are probably related to the location and type of retinal detachments in this cohort of premature infants. In all five eyes with stage 4A ROP, retinal traction was evident in the peripheral retina. Several studies have suggested that the effect of SB in stage 4 ROP is to mechanically minimize traction by scleral indentation and to reduce neovascular activity of peripheral proliferation [6, 20]. Due to previous laser treatment and the presence of tractional retinal forces in six of seven eyes, no further intravitreal anti-VEGF injections were performed, in order to avoid further fibrosis and worsening of traction [21]. Apart from the mechanical effect of SB on reducing the tractional retinal forces, fluorescence angiography has shown that SB additionally stabilizes the neovascular activity of fibrovascular tissue [20]. It has been suggested that SB leads to VEGF downregulation by relieving mechanical stress and by improving the oxygen supply from the choroid to the retina [20].

Retinal reattachment was also achieved in infant #4, who presented with stage 4B ROP after ranibizumab injection and had no evidence of traction. Although no peripheral break was found in funduscopy, it cannot be excluded that the inferior retinal detachment in this case was rhegmatogenous. Peripheral retinal breaks in ROP may occur from traction on the thin retina, in atrophic areas such as laser spots, or as a consequence of intravitreal injections [7]. SB is indeed indicated in rhegmatogenous retinal detachments from peripheral breaks, as it supports peripheral traction with indentation of the globe and promotes consequent retinal reattachment without removing the lens [22]. SB was also effective in infant #3, who was initially treated with systemic steroids for management of post-laser exudative retinal detachment [23, 24].

Apart from the indications of SB surgery in ROP, the main reason for employing this technique in the present study, is that SB surgery requires minimal equipment and is associated with more affordable costs [25]. The economic crisis has posed a considerable burden on the Greek public healthcare system, and even tertiary referral centers face severe shortages of medical equipment. On the other hand, vitrectomy requires more specialized and costly equipment. A comparison of the costs of scleral buckling and pars-plana vitrectomy (PPV) for adult retinal detachments found that, considering all costs, including eventual cataract surgery, scleral buckling procedures were 10.7% less expensive than PPV for retinal detachment repair in phakic patients [25]. Of note, our tertiary referral center is the only public center in Greece that offers pediatric vitreoretinal surgery.

On the other hand, SB surgery has several disadvantages. There are intraoperative complications, such as risk of scleral perforation due to the reduced thickness of the infant sclera [11, 12]. Removal or division of the buckle with a second surgery is required after 3–6 months, in order to reduce myopia and promote eye growth [11, 12]. Axial elongation and forward shift of the lens lead to axial and lenticular high myopia, which predisposes to amblyopia

[26]. The average postoperative refractive error in adults undergoing encircling SB is -2.75 D [26]. However, postoperative myopia in infants with ROP is much greater (mean, − 22 D), which often improves by about 5 D following sectioning of the buckle [8, 27]. It has been reported that the refractive error after SB removal in infants with ROP ranges from + 1.25 D to -20 D [8, 26, 27]. Consistent with previous studies, the average final myopic error after buckle removal in the present series was − 7.5 D, ranging from − 3 D to -14 D [8, 28]. High myopia may cause ametropic and anisometropic amblyopia in unilateral cases, as in infants #2 and #4.

Regarding the functional outcome, five of seven eyes achieved a fix and follow vision, one eye had central steady and maintained fixation and one eye had central steady and unmaintained fixation. Although these findings are in general favorable, longer follow-up is needed to provide more accurate estimates of visual acuity. Most authors agree that scleral buckling can successfully reattach the retina in stages 4A and 4B, but the functional results are variable and often disappointing. Hinz et al. reported a 75% success rate after SB surgery in 4A ROP eyes, with two eyes having a light perception (LP) acuity and five eyes achieving vision better than LP [28]. Visual acuity at 4.5-years by Gilbert et al. for eyes that were stage 4A at 3 months were extremely poor, with only 6 (18%) of 34 having better than 20/200 visual acuity and 22 (65%) being termed “blind” (light perception, no light perception, hand motions) [1].

One of the causes for reduced visual function in this series was optic atrophy. Two of seven eyes (infants #1 and #3) developed temporal optic disc pallor. Optic atrophy in premature infants with ROP-related retinal detachments may result from prematurity, or as a sequelae of laser ablation, ocular surgery, or postoperative inflammation in the developing retina. In a study of 272 children with optic atrophy, complications from premature birth were the most frequent etiology of optic atrophy (n = 44, 16%), with 68% of premature infants having a history of intraventricular hemorrhage [29].

Additionally, poor ocular perfusion pressure (due to reduced mean blood pressure under anesthesia and elevated intraocular pressure during ocular surgery) may also lead to optic atrophy [30]. Furthermore, it is unclear if the detached retina and incomplete vascularization may lead to retinal degeneration due to poor diffusion of nutrients, especially when the macula is detached [30]. Further macular pathology of the premature retina, such as cystoid macular edema in infant #3 (Fig. 2), which may go undetected in routine fundoscopy, can also contribute to reduced vision.

This study should be viewed in the light of some limitations, such as non-randomization. ROP is a multifactorial disease and the heterogeneity in patient population makes the comparison of studies extremely difficult, and partly explains the differences in success rates and visual outcomes. Due to its unique nature and the complexity of therapeutic approaches there is no prospective study that directly compares SB and LSV. This study did not aim to compare anatomic outcomes between two different surgical methods, but to highlight the outcome in cases where SB was the only available treatment. Further study is needed to determine the effect of this surgical approach on long-term visual development.

In summary, the choice of surgical method depends on severity of ROP, presence of plus disease or neovascularization (the vascular activity of the disease), retrolental involvement, nature of vitreoretinal traction and type of retinal detachment (exudative or rhegmatogenous component). This study focuses on the management of retinal detachments with peripheral traction in premature infants with comorbidities, where SB was the only available surgical modality. In this mini case series, anatomic reattachment was achieved in all eyes after SB and the result was maintained for the next 2 years. We conclude that SB continues to deserve a place in the armamentarium for ROP-related retinal detachment repair. SB is effective in appropriately selected cases, it involves no intraocular surgery, results in no cataract formation, and is economically cost-effective. Characteristics and comorbidities of premature infants as well as the available resources are potential factors associated with treatment of choice and general outcomes.

# Declarations

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**Authors' contributions:** All authors contributed equally to this work

**Ethics approval:** This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Ethics Committee of University Hospital of Larissa

**Consent to participate:** Written informed consent was obtained from the patients' parents

**Consent for publication:** Patients' parents signed informed consent regarding publishing their data and photographs.

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# Figures

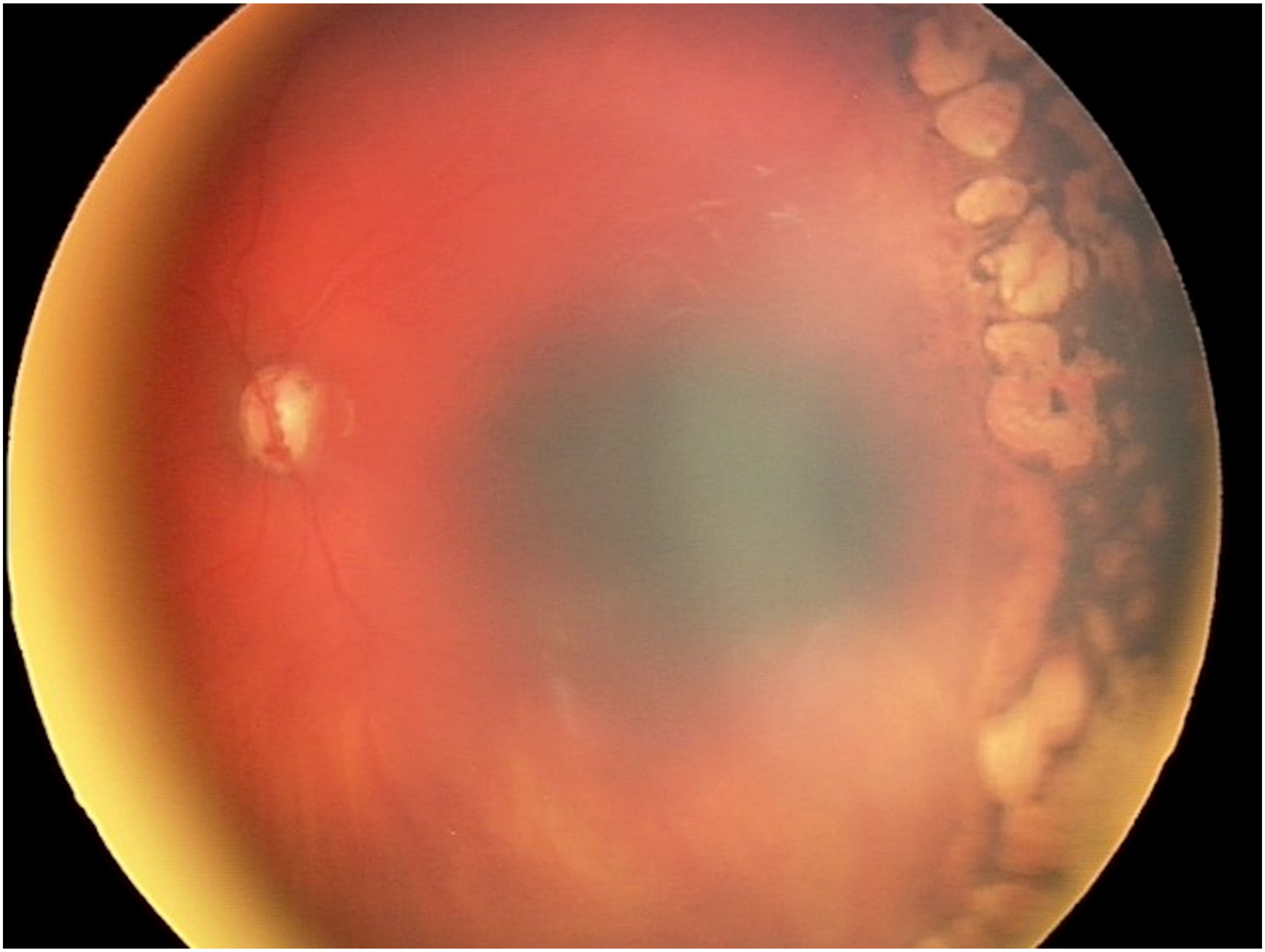

**Figure 1**

Resolved temporal retinal detachment in the left eye and temporal disc pallor 3 months after SB removal.

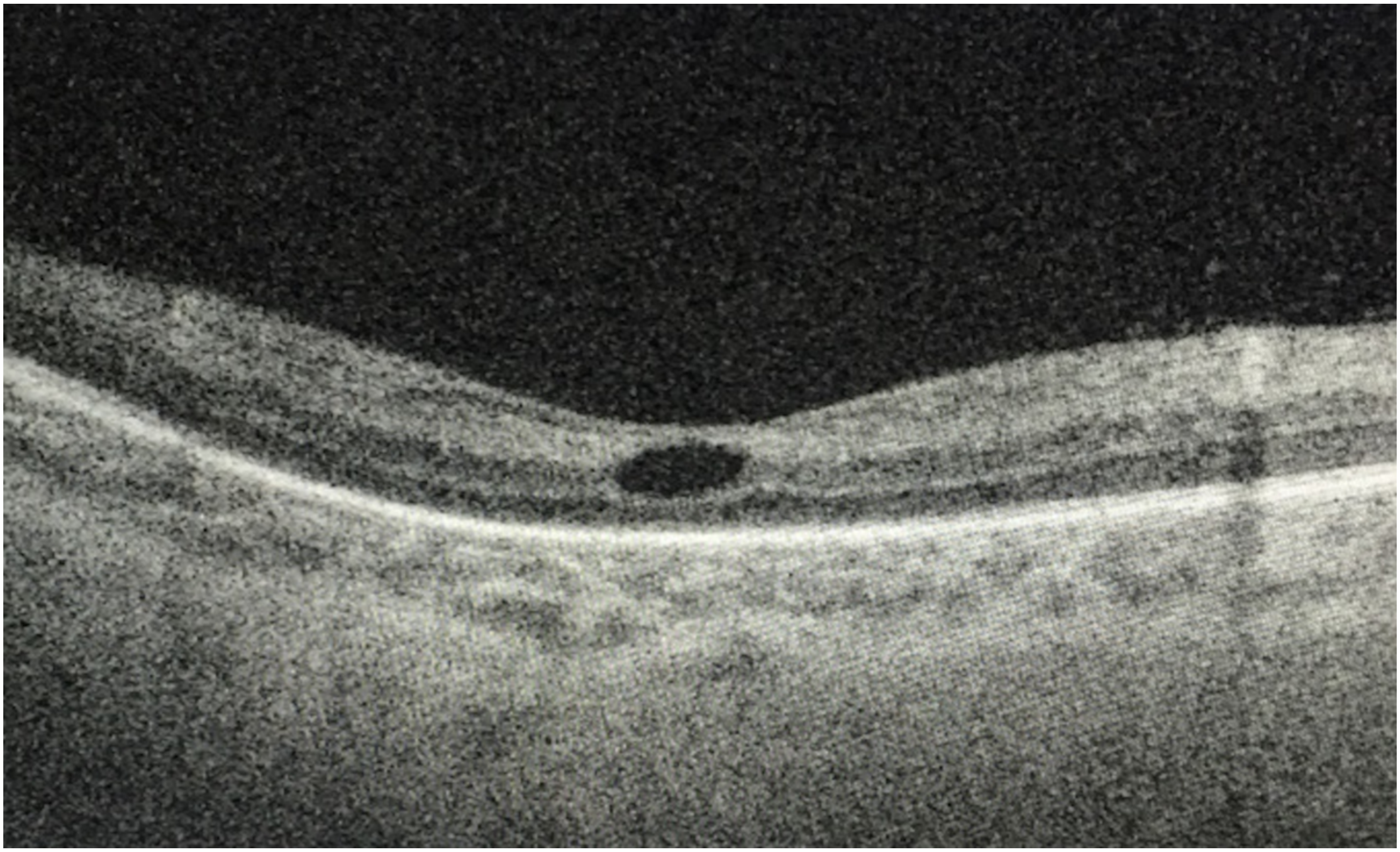

**Figure 2**

Swept-source optical coherence tomography (SS-OCT) in Case 3 obtained before SB: Cystoid macular edema with a single subfoveal cystoid structure is present in the left eye.

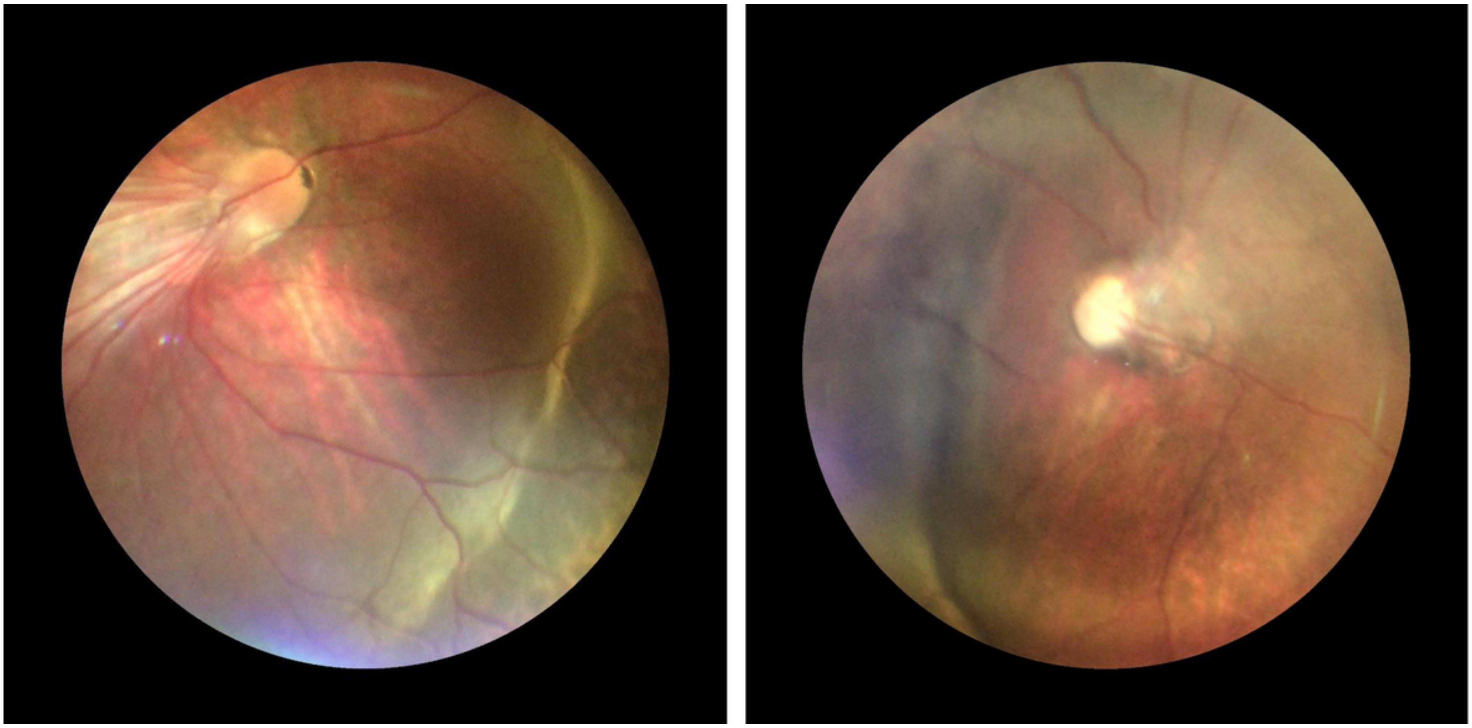

**Figure 3**

Fundus photography from Case 3 obtained 6 months after SB placement: A. The SB and the area of resolved retinal detachment are seen in the nasal periphery of the right eye. There is also temporal dragging of the disc and straightened blood vessels. B. The retina has attached on the nasal periphery of the left eye and there is also disc pallor and some degree of peripapillary atrophy.